

Appl. No. 10/090,517
Atty. Docket No. 8866
Amendment dated 11/03/2004
Reply to Office Action of 09/03/2004
Customer No. 27752

REMARKS

Claims 1-12, 14-24 and 26 are pending in the present application. No additional claims fee is believed to be due.

Rejection Under 35 USC 102(b) over Yanagida et al. (US 6,024,941)

The present invention describes skin care compositions with improved retinoid stability, comprising a retinoid; a preservative selected, from among others, phenols; and a dermatologically acceptable carrier. A further important aspect of the present invention is that the compositions are essentially free of parahydroxybenzoic acid esters, examples of which include methylparaben, ethylparaben, propylparaben, isopropylparaben and butylparaben.

The Office Action rejects Claims 1-6, 9-11 and 26 under 35 USC 102(b) as being anticipated by Yanagida et al. (US 6,024,941, hereinafter "Yanagida"). Yanagida teaches stable cosmetic compositions wherein vitamin A is stabilized by phenols, including BHA and BHT.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987); MPEP 2131.

Applicants submit that rejection of the instant claims under 35 USC 102(b) is improper, because Yanagida fails to teach each and every claim of Applicants' invention.

First, Applicants respectfully point out that in the first Office Action, these claims also were rejected under 35 USC 102(e) as being anticipated by Deckers et al. (US 6,582,710, hereinafter "Deckers"). The Office Action asserted that Deckers teach a cosmetic composition comprising vitamin A and phenol compounds BHA and BHT. Applicants explained that Example 12 in Deckers contains Phenonip, which according to *CTFA Cosmetic Ingredient Dictionary and Handbook*, contains phenoxyethanol, methylparaben, ethylparaben, butylparaben and propylparaben. Therefore, Deckers failed to teach each and every element of Applicants' claimed invention because the composition is not substantially free of parahydroxybenzoic acid esters. The Office Action found this argument persuasive and withdrew this rejection. Applicants point out that Yanagida similarly teaches compositions containing the parahydroxybenzoic acid esters

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methylparaben and ethylparaben. (See, for example, Yanagida, columns 11-14, table 1-2 and table 1-3, and examples 1-8, 1-12, 1-13 and further.) Therefore, Yanagida also fails to teach each and every claim of Applicants' invention. Applicants respectfully submit that because the Office Action found the argument regarding the examples in Deckers persuasive, and because this argument also applies to Yanagida, this rejection with respect to Yanagida also must be withdrawn.

Second, Applicants previously argued that Yanagida fails to anticipate the present invention, because Yanagida fails to teach Applicants' element of preservatives. Applicants asserted that BHA and BHT, though phenols, are antioxidants rather than preservatives. This Office Action rejects this argument, asserting that BHA and BHT fall under the specification's definition of phenols. The Office Action cites page 7, lines 20-21 of the specification, which defines phenols as "synthetic or natural aromatic compounds that carry at least one -OH group on an aromatic ring." The Office Action further asserts that the specification does not provide a particular definition for "preservatives" that would exclude BHA and BHT. Applicants respectfully traverse this assertion, and point out that the specification does sufficiently define the term "preservative" to distinguish BHA and BHT.

The specification clearly distinguishes between protecting compositions against oxidation and protecting against microorganism growth. On page 2, lines 15 - 17, the specification states:

Degradation caused by *oxidation* may be at least partially alleviated by careful processing in an oxygen-free environment and oxygen impermeable packaging. (Emphasis added.)

The specification then addresses the issue of microorganism growth, to which the use of preservatives is directed:

An added concern in personal care compositions, including those containing vitamins such as retinoids, is the potential for microorganism growth within the composition ... For this reason, nearly every personal care product currently marketed contains at least one *preservative* to impede or eliminate the growth of unwanted organisms that may contaminate the product under normal use conditions. Specification, page 2, lines 20 - 28 (emphasis added).

On page 7, lines 13-14, the specification defines preservative:

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As used herein, the term "preservative," refers to any ingredient that protects a product from the effects of microbiological contamination.

Applicants respectfully point out that as antioxidants, BHA and BHT exhibit minimal, if any, antimicrobial properties.

Some information has been published concerning the antimicrobial properties of antioxidants. However, adding antioxidants to formulations does little to aid product preservation. Rather, antioxidants are added to prevent the degradation of ingredients by oxidation.

Steinberg, D.C. *Preservatives for Cosmetics*. Allured Publishing Corporation (1996), p. 25. Applicants submit that the Office Action's assertion that antioxidants would be considered a preservative, because they would preserve a compound from oxidation, is incorrect. These antioxidants cannot be considered a "preservative," because as defined in the present invention, a preservative protects against anti-microbial activity.

A patentee may be his own lexicographer and grammarian. He "may define his own terms, regardless of common or technical meaning...Fairness to any patentee requires a court to accept his definition of words, phrases and terms." *Rohm & Haas Co. v. Dawson Chemical Co., Inc.*, 557 F. Supp 739, 217 U.S.P.Q. 515, 573 (Tex. 1983).

Yanagida fails to teach a preservative as defined by the Applicants, and thus fails to teach each and every element of the presently claimed invention.

In summary, Yanagida fails to anticipate the present invention for two reasons. First, Yanagida teaches compositions that include methyl and ethyl paraben, and thus fails to teach the Applicants' element of "essentially free of parahydroxybenzoic acid esters." This argument, which was found persuasive in regard to Decker, also applies to Yanagida. Second, Yanagida fails to teach the presently claimed element of preservatives, because BHA and BHT are not preservatives as defined by Applicants. For these reasons, Applicants respectfully request that the rejection under 35 USC 102(b) be reconsidered and withdrawn.

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Rejection Under 35 USC §103(a) Over Yanagida et al. (US 6,024,941) in view of Oblong et al. (US 5,939,082) and Bissett et al. (US 5,821,237)

The Office Action rejects Claims 1-12, 14-24 and 26 under 35 USC 103(a) as being unpatentable over Yanagida et al. (US 6,024,941) in view of Oblong et al. (US 5,939,082, hereinafter "Oblong") and Bissett et al. (US 5,821,237, hereinafter "Bissett").

Yanagida teaches stable cosmetic compositions wherein vitamin A is stabilized by a stabilizer selected from a group of compounds that includes phenols. The Office Action asserts that Yanagida does not expressly teach to exclude parahydroxybenzoic acid ester or formaldehyde and formaldehyde donating compounds, or to employ particular vitamin A derivatives, such as retinyl propionate, or to employ a particular preservative, such as *o*-phenylphenol; however that Yanagida does not *require* the presence of parahydroxybenzoic acid esters, or formaldehyde, or its donating compounds. The Office Action asserts that Oblong teaches that synthetic or natural vitamin analogs, such as retinol esters, are well-known in the art for use as vitamin A in cosmetic compositions. The Office Action further asserts that Bissett teaches that the preservatives in the present invention, such as *o*-phenylphenol and dehydroacetic acid, are well-known preservatives. The Office Action concludes that it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the claimed invention to make cosmetic compositions containing the vitamin A compound retinyl propionate, without using parahydroxybenzoic acid ester and formaldehyde donating compounds, and which employ *o*-phenylphenol as a preservative. Applicants respectfully traverse this rejection based on the following arguments.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. *In re Vaack*, 20 USPQ2d 1438.

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a. There is no suggestion of motivation to combine the references.

Oblong describes skin care compositions containing vitamin B3 compounds, for example, niacinamide. Whereas Oblong discusses the use of vitamin A compounds in conjunction with vitamin B3, this combination is for a purpose unrelated to the present invention. The Office Action refers to column 22, lines 26-52; however, referring to lines 2-8 of this same column:

The vitamin B3 compound and retinoid provide unexpected benefits in regulating skin condition ... it is believed that the vitamin B3 compound increases the conversion of certain retinoids to trans-retinoic acid ...

Thus, Oblong suggests the use of retinoids in combination with vitamin B3 for the purpose of effecting a *conversion* of the retinoid to trans-retinoic acid. The purpose of the present invention, however, is to *stabilize* the vitamin A compounds. Therefore, Oblong teaches away from the use of retinoids in the context of the present invention.

Similarly, whereas Bissett describes compositions which are substantially free of formaldehyde or formaldehyde-donating compounds, the purpose is unrelated to Applicants' compositions. In Bissett, the invention was directed toward stabilization of sulfhydryl compounds (i.e. a highly reactive -SH group). Bissett states in Column 14, line 67 through Column 15, line 8:

[I]t has been found that formaldehyde can chemically react with the sulfhydryl compound to decrease its activity. Thus, when a composition containing the sulfhydryl compound is formulated with formaldehyde or a formaldehyde forming preservative or other material, the composition may have decreased activity of the sulfhydryl compound over time relative to the corresponding formulation that does not contain formaldehyde or a compound capable of forming formaldehyde.

Retinoids contain no sulfhydryl groups. The reactive species in retinoids is oxygen-containing; therefore, the issue with retinoids is to prevent oxidation.

In summary, there is no motivation or suggestion to combine either Oblong or Bissett with Yanagida. Both Oblong and Bissett teach away from this combination. Oblong teaches the use of retinoids in combination with vitamin B3 to effect a conversion, rather than a stabilization. Bissett teaches avoiding formaldehyde or formaldehyde-donating compounds with highly reactive sulfhydryl-containing compounds, and makes no mention of prevention of oxidation. Finally, whereas Bissett makes a passing reference

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to *o*-phenylphenol as a preservative, there is nothing to suggest that the use of this preservative is preferable to any of the others, in particular for the purpose of stabilizing retinoids. Therefore, one of ordinary skill in the art at the time of the invention would not have been at all motivated to combine the references.

b. There is no reasonable expectation of success.

Applicants describe compositions exhibiting increased stability of vitamin A. On page 14, lines 30-34 of the specification, Applicants state:

In order to evaluate the stability of a retinoid in a given composition, the composition may be placed in a container that limits the free flow of oxygen ... and stored for 12 weeks at a constant 40°C and the percentage loss measured after an elapsed time period.

In contrast, the stability of the compositions in Yanagida were measured over periods of five days, 10 days, two weeks and four weeks. (See, for example, Yanagida, columns 12- 17). The compositions in Yanagida contain parahydroxybenzoic acid esters. Clearly, therefore, Applicants could have no reasonable expectation of successfully producing compositions that are stable for a period of at least twelve weeks by using the teachings of Yanagida. Nor could Applicants reasonably expect to be successful by combining the cited references. All teach the use of methyl- and ethylparaben. In Oblong, rather than being stable at all, the retinoids are converted to trans-retinoic acid. There simply is nothing in the cited art to suggest that one of skill in the art could reasonably expect to increase the stability of retinoids in skin care compositions by combining these references.

c. The cited art fails to teach or suggest all the claim limitations.

Applicants describe skin care compositions with improved retinoid stability, comprising a retinoid; a preservative selected, from among others, phenols; and a dermatologically acceptable carrier; and which are essentially free of parahydroxybenzoic acid esters. As discussed above, Yanagida fails to teach a preservative, as defined by Applicants. All of the cited references teach compositions that contain methyl- and ethylparaben, which are examples of parahydroxybenzoic acid esters. Therefore, the combination of references fails to teach or suggest all of the claim limitations.

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Applicants point out that in order to establish a *prima facie* case of obviousness, the Office Action must establish all three of the criteria set forth in *In re Vaack*. Applicants respectfully submit that the Office Action fails to establish *any* of these criteria. Applicants therefore respectfully request that the claim rejections under 35 USC 103(a) be reconsidered and withdrawn.

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Conclusion

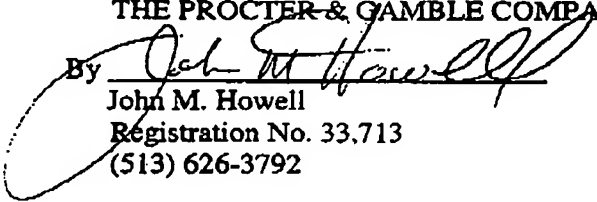
In light of the above remarks, it is requested that the Examiner reconsider and withdraw the rejection under 35 USC 102(b) and 35 USC 103(a). Early and favorable action in the case is respectfully requested.

This response represents an earnest effort to place the application in proper form and to distinguish the invention as now claimed from the applied references. In view of the foregoing, reconsideration of this application and allowance of Claims 1-12, 14-24 and Claim 26 is respectfully requested.

Respectfully submitted,

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